PATENT/Docket No. PC28117A
Appl. No. 10/776,337
Filing Date: 2/12/2004

REMARKS

I. Preliminary Remarks

In the Office Action, Claims 1-28 are pending and under examination. All claims are subject to a requirement for restriction. After entry of this paper, Claims 2, 4-8, 13-14, 16 and 18 (partially), are under consideration. Claims 1, 3, 9-12, 15, 17, 18 (partially), and 19-28 are withdrawn, with traverse and without prejudice in an effort to favorably advance prosecution of the present application. Applicants reserve the right to petition for rejoinder should the circumstances allow, or to pursue the subject matter of the withdrawn claims in a divisional application. However, reconsideration and withdrawal of the restriction requirement are solicited for the reasons set out below.

This Response addresses the Examiner's restriction requirement. Applicants therefore respectfully submit that the present application is in condition for examination on the merits. Favorable consideration of all pending claims is respectfully requested.

This Response is timely filed. The USPTO is given authorization to charge Deposit Account No. 21-0718 for any fees necessary with the submission of this Response.

II. Remarks/Arguments

In the Office Action, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following three separate and distinct inventions:

I. Claims 1, 3, 9-12, 15, 17 and 18, drawn to a compound of formula I, which is form II, classified in class 548/486.

II. Claims 2, 4-8, 13-14, 16 and 18, drawn to a compound of formula I, which is form I, classified in class 548/486.

III. Claims 19-28, drawn to a method of using a compound of formula (I), classified in class 514/414.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect, with traverse, to prosecute the subject matter of Group II, Claims 2, 4-8, 13-14, 16 and 18 (partially), drawn to a compound of formula I, which is form I, classified in class 548/486.

Applicants conditionally withdraw Claims 1, 3, 9-12, 15, 17, 18 (partially), and 19-28 with traverse and without prejudice. Applicants reserve the right to petition for rejoinder by way of amendment pursuant to 37 CFR 1.121 should the circumstances allow, or file one or more divisional applications directed to the non-elected subject matter in this Application.

However, pursuant to 37 CFR 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" enough so as to justify the restriction requirement.

As stated by the Examiner: "Inventions I and II are unrelated polymorphs. Compounds are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP 806.04, MPEP 808.01). In the instant case, the claims of Inventions I and II are drawn to polymorphs with different PXRD patterns." Applicants respectfully submit that while the polymorphs exhibit different PXRD patterns, they are not unrelated. They are related in that they are different solid phases of the same substance: 5-(5-fluoro-2-oxo-1,2-dihydro-indol-3-ylidenemethyl-2,4-dimethyl-1H-pyrrole-3-carboxylic acid (2-pyrrolidin-1-yl-ethyl)-amide. As stated in the specification, "'Polymorph' refers to a solid phase of a substance, which occurs in several distinct forms due to different arrangements and/or conformations of the molecules in the crystal lattice. A polymorph may also be defined as different unsolvated crystal forms of a compound. Polymorphs typically have different chemical and physical properties..."

In addition, for the Groups to be unrelated, it must be shown that "they are not disclosed as capable of use together." However, in the specification, it is stated: "In the preferred embodiments of the present invention, pure, single polymorphs as well as mixtures comprising two or more different polymorphs are contemplated...." Thus, although polymorphs may have and may be distinguished by different physical, chemical, or mechanical properties, the polymorph I and polymorph II forms are related in that they are different solid phases of the same substance, and are disclosed as being capable of use together. (see paragraphs 0024 through 0028, inclusive, for complete discussion)

The courts have recognized that it is in the public interest to permit Applicants to claim several aspects of their invention together in one application, as the Applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. § 112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl 456 F.2d 658, 666, 117 U.S.P.Q. 250,256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

In addition, this restriction is improper because prosecution of the restricted subject matter in one application would not place a serious burden on the Examiner. According to MPEP § 803, the Examiner can only restrict patentable distinct inventions when (1) the inventions are independent or distinct as claimed; and (2) where there is a serious burden on the Examiner if restriction is not required. Applicants respectfully submit that the Examiner has made no showing that prosecuting the claims of the invention in one application would be burdensome. Groups I-III are all directed to similar subject matter. In fact, Groups I and II are directed to the same class and subclass. Therefore, it is respectfully submitted that it would not constitute undue burden on the Examiner for the claims of all the groups to be maintained in a single application and for all three groups to be examined together. It is respectfully submitted that prosecution of

all of these groups of claims in a single application would be efficient, thereby promoting the grounds for the establishment of the restriction requirement practice.

Applicants further respectfully suggest that in view of the continued increase of official fees and the potential limitation of Applicants' financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

III. Conclusion

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

Timothy Gumbleton Date: October 26, 2006

Timothy J. Gumbleton, Patent Agent
Registration No. 54,143

Pfizer Inc., Patent Department
7000 Portage Road
Kalamazoo, Michigan 49001
Telephone No. (269) 833-2501 or (269) 833-9500
Telefax No. (269) 833-8897